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| APPLICATION NO.                        | FILING DATE                 | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-----------------------------|----------------------|---------------------|------------------|
| 10/613,335                             | 07/03/2003                  | Walter A. Zohmann    | 10012.7             | 5090             |
| 21999<br>KIRTON AND                    | 7590 04/10/2007<br>MCCONKIE | EXAMINER             |                     |                  |
| 60 EAST SOU                            | TH TEMPLE,                  | THANH, LOAN H        |                     |                  |
| SUITE 1800<br>SALT LAKE CITY, UT 84111 |                             |                      | ART UNIT            | PAPER NUMBER     |
| ,                                      |                             |                      | 3763                |                  |
| ·                                      |                             |                      | •                   |                  |
| SHORTENED STATUTOR                     | Y PERIOD OF RESPONSE        | MAIL DATE            | DELIVERY MODE       |                  |
| 3 MONTHS 04/10/2007                    |                             |                      | DAI                 | DED              |

# Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Application No.   Applicant(s)   Vol.  |   |  |   | <i></i>   |  |  |  |
|--|---|--|---|---|--|--|--|
| Examiner LoAn H. Thanh  The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  Editorisons of time may be available under the provisions of 37 CFR 1.198(a). In no event, however, may a reply be timely filed after Str. (by MONTHS from the mailing date of this communication.  If NO period for reply is apecified above, the maximum statutory period will apply and will expire Str. (by MONTHS from the mailing date of this communication.  If NO period for reply is apecified above, the maximum statutory period will apply and will expire 31% (by MONTHS from the mailing date of this communication. If NO period for reply with the set or extended period in communication.  If NO period for reply is appected above, the maximum statutory period will apply and will expire Str. (by MONTHS from the mailing date of this communication. If NO period for reply with the set of resply with the set of the communication. Even if simply filed, may reduce any served patent term adjustment. Set 97 CFR 1.1704(b).  Status  1) Responsive to communication(s) filed on 12 January 2007.  2a) This action is FINAL. 2b) This action is non-final.  3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims  4) Claim(s) 1-9 Is/are pending in the application.  4) Claim(s) 1-9 Is/are allowed.  6) Claim(s) 1-9 Is/are rejected.  7) Claim(s) is/are allowed.  6) Claim(s) 1-9 Is/are rejected to by the Examiner.  Application Papers  9) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Application Papers  9) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Application promet the available and the principal provinty          |   |  | Application No.   | Applicant(s)  |  |  |  |
| LOAN H. Thanh  3763  - The MAILING DATE of this communication appears on the cover sheet with the correspondence address -  Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  Eletheating of time may be available under the provisions of 37 CFR 1396). In no event, however, may a veryle be timely filed after Six (6) MONTHS from the mailing date of this communication.  If NO period for reply is specified above, the measure statutory period will apply and will expire Six (8) MONTHS from the mailing date of this communication.  Fellure to reply within the set or extended period for reply will, by stability, cause the application to become ABANDONED (35 U.S.C. § 133).  Fellure to reply within the set or extended period for reply will, by stability, cause the application to become ABANDONED (35 U.S.C. § 133).  Fellure to reply will the set or extended period for reply will, by stability, cause the application to become ABANDONED (35 U.S.C. § 133).  Fellure to reply will the set or extended period for reply will, by stability, cause the application to become ABANDONED (35 U.S.C. § 133).  Fellure to reply will the set or extended period for reply will, by stability, cause the application to become ABANDONED (35 U.S.C. § 133).  Fellure to reply will the set or extended period for reply will septe 51X (8) MONTHS from the mailing date of this communication.  1) A set of the period will apply and the set of the some file of the set of the se | Office Astism Comm                        |  | 10/613,335  |   |  |  |  |
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| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be time placed after Six (or MONTHS from the mailing date of this communication. If the period from you is specified above, the maximum statutory period will apply and ill earlies Six (S) MONTHS from the mailing date of this communication. If the period from you is specified above, the maximum statutory period will apply and ill earlies Six (S) MONTHS from the mailing date of this communication. If the period from your is specified above, the maximum statutory period will apply and ill earlies Six (S) MONTHS from the mailing date of this communication to be solved. ADAMDONED (cs. U.S.C. § 13.3):  Any reply received by the Office alter than three menths after the mailing date of this communication, even if timely filed, may reduce any amend patent term adjustment. See 37 CFR 1.704(b).  Status  1) □ Responsive to communication(s) filed on 12 January 2007.  2a) □ This action is FINAL.  2b) □ This action is non-final.  3) □ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims  4) □ Claim(s) 1-9 is/are pending in the application.  4a) Of the above claim(s) is/are allowed.  6) □ Claim(s) 1-9 is/are allowed.  7) □ Claim(s) 1-9 is/are allowed.  8) □ Claim(s) 1-9 is/are allowed.  9) □ The specification is objected to by the Examiner.  10 □ □ The drawing(s) filed on is/are allowed.  11 □ The drawing(s) filed on is/are allowed.  12 □ Claim(s) 1-9 is/are allowed.  13 □ The drawing sheet(s) including the correction is required if the drawing(s) is objected to See 37 CFR 1.121(d).  11 □ The oath or declaration is objected to by the Examiner. Note the attached Office Ac                            | T   |  |   | 1   |  |  |  |
| WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  Extensions of time may be available under the provisions of 37 CFR 1.33(a). In oe ovent, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is selected above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. If NO period to reply will make a selected period for reply will by statute, causes the application to secome ARANDONED (35 U.S.C. § 135). It is action in the mailing date of this communication, even if timely filed, may reduce any searned patent term adjustment. See 37 CFR 1.704(b). Baffer the mailing date of this communication, even if timely filed, may reduce any searned patent term adjustment. See 37 CFR 1.704(b). Baffer the mailing date of this communication, even if timely filed, may reduce any searned patent term adjustment. See 37 CFR 1.704(b). Baffer the mailing date of this communication, even if timely filed, may reduce any searned patent term adjustment. See 37 CFR 1.704(b). Baffer the mailing date of this communication, even if timely filed, may reduce any searned patent term adjustment. See 37 CFR 1.704(b). Baffer the mailing date of this communication is consistent to the mailing date of this communication.  1) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims  4) Claim(s) is/are pending in the application.  4) Claim(s) is/are pending in the application.  4) Claim(s) is/are pending in the application.  4) Claim(s) is/are allowed.  6) Claim(s) is/are allowed.  6) Claim(s) is/are allowed.  7) Claim(s) is/are objected to by the Examiner.  10) The drawing(s) filed on is/are: allowed.  10) The drawing(s) filed on is/are: allowed.  11) T   | Period fo                                 | The MAILING DATE of this communication app<br>or Reply   | pears on the cover sheet w  | ith the correspondence address  |  |  |  |
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|  | a)[                                       | <ul> <li>All b) Some * c) None of:</li> <li>1 Certified copies of the priority documents</li> <li>2 Certified copies of the priority documents</li> <li>3 Copies of the certified copies of the priority application from the International Bureau</li> </ul>  | es have been received.  Es have been received in A  Trity documents have been  U (PCT Rule 17.2(a)).                                | Application No  received in this National Stage   |  |  |  |
|  |   |  | •   | •   |  |  |  |
| Attachment(s)  | Attachment                                | (s)  |   |   |  |  |  |
| 1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)  |   |  |   |   |  |  |  |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date  5) Notice of Informal Patent Application  Other:  | 3) 🔲 Inform                               | nation Disclosure Statement(s) (PTO/SB/08)   | 5) 🔲 Notice of I  |   |  |  |  |

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#### **DETAILED ACTION**

## Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/12/07 has been entered.

### Response to Amendment

Applicant has only argued and have not amended the claims.

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zohmann ( USPN 6,558,353) in view of Sorenson et al. (USPAP 2002/0123723).

Zohmann discloses the invention as substantially claimed. Zohmann discloses a needle apparatus for administering a peripheral nerve block comprising a hollow needle 50 having a fenestration/side port 54, a needle hub 40 and a stylet cap 20 coupled to a

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stylet 30 and slidable within the needle 50 and needle hub 40. Zohmann also discloses at least one fenestration indicator 48,48 for visual and tactual verification of the orientation of the fenestration. See figures 1-8, columns 5-8. However, Zohmann does not disclose a plurality of fenestrations. Sorenson et al. discloses a plurality of holes alternating along the length of the needle and longitudinally spaced on alternate sides of the wall with an obturator/stylet 55 to block passage of fluid while the needle is being inserted into the patient. The holes/fenestrations are provided for uniform and optimal dispersion of medication across a range of proximal absorption fields. It would have been obvious to one of ordinary skill in the medical injection art to modify the single fenestration of Zohmann with a plurality of fenestrations as taught by Sorenson et al. to provide a uniform volume and rate of dispersion of therapeutic fluids from the fluid flow path to the target area.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zohmann (USPN 6,558,353) in view of Yang (CN –2201946-Y).

Zohmann discloses the invention as substantially claimed. Zohmann discloses a needle apparatus for administering a peripheral nerve block comprising a hollow needle 50 having a fenestration/side port 54, a needle hub 40 and a stylet cap 20 coupled to a stylet 30 and slidable within the needle 50 and needle hub 40. Zohmann also discloses at least one fenestration indicator 48,48 for visual and tactual verification of the orientation of the fenestration. See figures 1-8, columns 5-8. Zohmann discloses a needle in combination with a stylet. However Zohmann shows one fenestration.

Zohmann is silent to a plurality of fenestrations. See Yang figure 1. Yang shows a

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needle with 3 fenestrations. It would have been obvious to one of ordinary skill at the time the invention was made to modify the needle of Zohmann with a plurality of fenestrations as taught by Yang in order to provide a plurality of infusion ports in order to provide increased flow to a larger local target area or in order to provide flow in case one of the fenestrations/ports is occluded.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zohmann ( USPN 6,558,353) in view of Ditto (US 7,022,109).

Zohmann discloses the invention as substantially claimed. See above. However, Zohmann does not disclose a plurality of fenestrations. Ditto discloses a plurality of holes 33 at the distal end to deliver medications to the epidural space. The holes/fenestrations are provided for uniform and optimal dispersion of medication and decrease of patient discomfort due to the pressure of the injection. The plurality of holes provides for the dispersion of the pressure. It would have been obvious to one of ordinary skill in the medical injection art to modify the single fenestration of Zohmann with a plurality of fenestrations as taught by Ditto to provide a uniform volume and rate of dispersion of therapeutic fluids with decreased discomfort to the patient by the decreased pressure of the injection via plural holes.

# Response to Arguments

Applicant's arguments filed 01/12/07 have been fully considered but they are not persuasive. Applicant's arguments are not convincing. The Examiner has used the teaching of the secondary references of Sorensen or Yang as teaching more than one aperture. The Examiner is not relying on the teaching of having a plurality of holes

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along the entire length as applicant is arguing. Zohmann discloses 1 port/aperture. The examiner is relying on the teaching of multiple ports at the distal end rather than one port in order to provide multiple outlets for delivery of the drug to the target site in order to provide a different port or path to the target site in case 1 port is blocked. The target site could still be the local target site and a plurality of holes at the distal end would provide uniform delivery.

### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is (571) 272-4966. The examiner can normally be reached on Mon. - Fri. (First Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LoAn H. Thanh Primary Examiner Art Unit 3763

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